

MAY 31 2002

K021403

Page 1 of 2

**BIOMET**  
CORPORATE HEADQUARTERS

**SUMMARY OF SAFETY AND EFFECTIVENESS**

**Applicant or Sponsor:** Biomet Orthopedics, Inc.  
P.O. Box 587  
Warsaw, IN 46581-0587

**Contact Person:** Dalene T. Binkley  
Telephone: (574) 267-6639

**Proprietary Name:** HA Mallory/Head® Porous Femoral Stem & HA Mallory/Head® Porous Lateralized Femoral Stem

**Common Name:** Prosthetic Hip Joint – Hydroxyapatite (HA) Coated Porous Femoral Stem

**Classification:** Prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate

**Device Classification:** Class II

**Legally Marketed Device to which Substantially Equivalence is Claimed:**  
Mallory/Head® Porous Femoral Stem 510(k)- K921181 and Mallory/Head® Lateralized Press-Fit Femorals 510(k)s- K000538 and K003429.

**Device Description:** The HA Mallory/Head® Porous Femoral Stems & HA Mallory/Head® Porous Lateralized Femoral Stems are the same as each of their predicate(s)- Mallory/Head® Femoral Stem 510(k)- K921181 and Mallory/Head® Lateralized Press-Fit Femorals 510(k)s- K000538 and K003429, except for the addition of Hydroxyapatite Coating and additional sizes for the standard femoral stems.

**Indications for Use:** The indications for the HA Mallory/Head® Porous Femoral Stems & HA Mallory/Head® Porous Lateralized Femoral Stems are for ) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) Rheumatoid arthritis; 3) Correction of functional deformity; 4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; and 5) Revision procedures where other treatments or devices have failed.

MAILING ADDRESS  
P.O. Box 587  
Warsaw, IN 46581-0587

SHIPPING ADDRESS  
56 E. Bell Drive  
Warsaw, IN 46582

OFFICE  
219.267.6639

FAX  
219.267.8137

E-MAIL  
biomet@biomet.com

00108

**Summary of Technologies:** The HA Mallory/Head® Porous Femoral Stems & HA Mallory/Head® Porous Lateralized Femoral Stems' components-the materials, design, sizing, and indications are similar or identical to the predicate devices.

**Non-Clinical Testing:** Mechanical Testing with an Engineering Justification determined that the HA Mallory/Head® Porous Femoral Stems & HA Mallory/Head® Porous Lateralized Femoral Stems' components presented no new risks and were, therefore, substantially equivalent to the predicate device.

**Clinical Testing:** No clinical testing was provided as a basis for substantial equivalence.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAY 31 2002**

Ms. Dalene T. Binkley  
Regulatory Affairs Specialist  
Biomet Orthopedics, Inc.  
P.O. Box 587  
Warsaw, IN 46581-0587

Re: K021403

Trade/Device Name: HA Mallory/Head® Porous Femoral Stem & HA Mallory/Head®  
Porous Lateralized Femoral Stem

Regulation Number: 21 CFR 888.3358

Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated  
uncemented prosthesis

Regulatory Class: II

Product Code: MEH, LPH

Dated: April 26, 2002

Received: May 2, 2002

Dear Ms. Binkley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

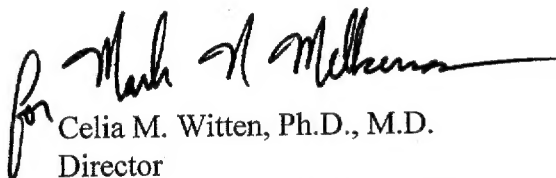
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.  
Director

Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K021403

DEVICE NAME: HA Mallory/Head® Porous Femoral Stem & HA Mallory/Head® Porous Lateralized Femoral Stem

INDICATIONS FOR USE:

The HA Mallory/Head® Porous Femoral Stem & HA Mallory/Head® Porous Lateralized Femoral Stem are indicated for use for 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) Rheumatoid arthritis; 3) Correction of functional deformity; 4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; and 5) Revision procedures where other treatments or devices have failed.

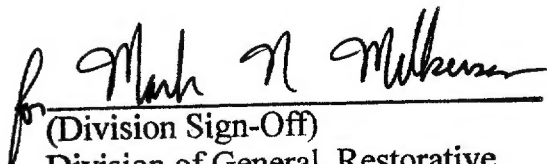
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use yes  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use No  
(Optional Format 1-2-96)

  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

510(k) Number K021403

00009